
GENERAL PROCEDURAL POLICIES

ROUTING OF
CONGRESSIONAL CORRESPONDENCE

Correspondence from Members of Congress will receive high priority attention from all Food and Drug Administration (FDA) personnel. The Office of Legislative Affairs (OLA) is responsible for replies to Congressional inquiries. In many instances, however, it is necessary for an incoming letter to be referred to the Center for preparation of a draft reply. Sometimes an inquiry is sent directly to the Center instead of through OLA. Procedures for handling these inquiries are provided in this guide. Additional information on the preparation of responses to Congressional inquiries is also provided in the FDA Staff Manual Guide (SMG) 2420.1.

NOTE: General Accounting Office (GAO), Inspector General (IG), House/Senate Appropriation requests and other Congressional inquiries related to budget are not "Congressional inquiries" as referred to in this policy. CVM has a separate routing process for these requests.

I. Purpose:

The purpose of this guide is to describe the procedures to be used when responding to inquiries from members of Congress.

II. Congressional Inquiries Received from OLA:

- A. Congressional inquiries (via letter or telephone) initially received by OLA and requiring CVM input will be directed to the Division of Compliance (HFV-230) by the OLA Correspondence Control Coordinator (HFW-10). HFV-230 will provide a "for your information" copy of the inquiry to CVM's Special Assistant to the Director.
- B. The Office of the Director, Division of Compliance, HFV-230, is the contact point within the Center for receipt and logging of the inquiry, coordination among offices if necessary, and monitoring timeliness of response. The preparation of a response to an inquiry may be assigned to any unit within the Center depending upon the expertise

involved. The expertise and resources required for response are determined by the Director, HFV-230, in conjunction with the appropriate Office Directors.

- C. The designated unit will prepare a draft reply, obtaining input from appropriate CVM or FDA staff as needed. The draft reply must respond to all issues raised in the incoming inquiry. Replies should be courteous, short, and to the point. Use non-technical language where possible unless the incoming letter indicates that the use of nontechnical language would be inappropriate. (This is consistent with SMG 2430.1-3 c,d.) The draft reply is then returned to HFV-230 for concurrence and handling.
- D. HFV-230 will send the original draft response to OLA (HFW-10); and will send copies to the Director, CVM (HFV-1) through the Director, Office of Surveillance and Compliance (HFV-200) as well as to the Special Assistant to the Director. One copy will be retained in HFV-230 files.
- E. OLA will then prepare the final response for issuance, providing copies to all offices specified on the draft.
- F. HFV-230 compares the final issuance with the draft copy to ensure that the substantive content or meaning has not been changed (if no conflicts exist, the draft copy may then be discarded). A copy of the issued letter is kept on file and a copy is provided to the Special Assistant to the Director.

III. Congressional Inquiries Received Directly by CVM Staff Members:

- A. Letters:
 - 1. Congressional letters and inquiries that are routed or sent directly to CVM staff members without going through OLA shall be hand carried to HFV-230.
 - 2. HFV-230 will provide the original incoming letter to HFW-10 for logging and jacketing, and HFV-230 will process as outlined above.
- B. Telephone Inquiries:
 - 1. All telephone inquiries from Congressional staff should be referred to the Special Assistant to the Director. The Special Assistant will coordinate the follow-up response with OLA.

IV. Response Time Frame:

- A. HFW-10 designates a due date for each Congressional inquiry transmitted to CVM for preparation of a draft response.
- B. Every reasonable effort should be made to meet the designated due date.
- C. If the due date cannot be met, HFV-230 must be notified prior to the due date, and the Division will request a time extension from HFW-10.